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TITLE: PREPARATION OF FREEZE-DRIED EMULSION DRUG

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ABSTRACT:

PURPOSE: To obtain the titled drug consisting of an easily soluble freeze-dried cake and containing redispersed oil droplets having sufficiently small size to enable the administration by intravenous injection, by dissolving a vehicle and a specific water-soluble polymer in the aqueous phase of an O/W-type emulsion, and freeze-drying the solution.

CONSTITUTION: A vehicle (e.g. saccharide, urea, etc.) and a water-soluble polymer selected from PVA, polyvinyl pyrrolidone, low-molecular weight gelatin, PEG, etc. are dissolved in the aqueous phase of an O/W-type emulsion. The obtained aqueous solution is mixed with an oil (e.g. soybean oil, linoleic acid, etc.) preferably at a ratio of (30~15):1, emulsified, and freeze-dried to obtain the objective drug preparation. The dissolution of the water-soluble polymer in the aqueous phase is effective to prevent the coagulation of the emulsion particles in the freeze-drying process, and accordingly, the obtained cake has excellent appearance and solubility and gives an emulsion having oil particle diameter of $\leq 2\sim 3\mu\text{m}$.

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